REMARKS/ARGUMENT

Objections to the Specification

Applicant has amended the specification from the term "transcriptional" to "transcription" and has also amended the specification to use the designator "SEQ ID NO.:" consistently throughout the specification when referring to specific nucleic or amino acid sequences. No new matter is included by this amendment and withdrawal of the objection is respectfully requested.

Rejections under 35 U.S.C. § 112, 2nd Paragraph

Applicant has amended the claims to delete specific references to the terms, "TFIIAα/β-like factor protein," "Stoned TFIIAα/β-like factor protein," and "substantially homologous," from the current claims. The dependency designations for claims 93 and 104 have been corrected. Withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 112, 1st Paragraph

The claims have been amended in light of the Written Description Guidelines ("Guidelines"). Specifically, the Applicant refers to the Guidelines as relate to Protein Variants and the amount of disclosure needed to support claims to "variants" that is, within certain levels of identity, e.g., 90, 95 or 98 percent.. As described in the Specification at pages 21-23, and FIGs 8A, 8B and 9 the transcription factors of the present invention are members of the TFIIA family of transcription factors that have certain conserved subunits and defined regions within and across species. Written description support is found in the specification, e.g., on pages 22-23:

> A schematic comparison of ALF and other TFIIA large subunit sequences from human (3, 4), Drosophila (9), Arabidopsis (Genbank Accession number X98861) and yeast (8) is shown in FIG 8A. These sequences share a common organization consisting of conserved regions I and IV, acidic region III and an internal nonconserved region II. ALF is similar to its human TFIIAα/β counterpart in region I (aa 1-54; 67%) and region IV (aa 417-478; 73%) and in the negatively-charged region III (aa ~340-414; 42% D/E residues). In contrast, region II shares no homology with the corresponding region [illegible] amino acids in length [illegible] contains

> region between amino acids 44 to 150 that is rich in proline (20%), serine (21%) and threonine (9%) residues. Residues between 275 and 692 display 47% similarity to the Drosophila Stoned B protein (39) and 46% similarity to an uncharacterized Stoned β-like ORF in C. elegans, C27H6.1 (53). The Drosophila stoned locus was first identified as a class of mutations that caused neurological defects such as temperature-sensitive paralysis (41) and it has been suggested that Stoned B functions in membrane trafficking in neurons (39). In addition, residues from 410 to 692 within the Stoned B-homology region are 33% and 37% similar to the mouse μ1 (AP47) and rat μ2(AP50) clathrin APs, respectively (FIG 7B) (42, 43). The μ1 (AP47) and μ2 (AP50) clathrin APs are subunits of the AP-1 and AP-2 complexes associated with the trans-Golgi and plasma membranes, respectively and function in the internalization, sorting and recycling of receptors and other membrane proteins (44, 45). Thus, the N-terminus of SALF is related to a family of proteins involved in membrane trafficking.

Therefore, the Guidelines are satisfied as to the level of variation that is known in the art. According to the specification, the percent identity relates to a protein having one or more amino acid substitutions, deletions, insertions and/or additions made to the protein of the present invention (e.g., page 16, lines 12 to 29). The specification and claims indicate what distinguishing attributes are shared by the members of the genus (see for example, page 16 as relates to the ALF protein of SEQ ID NO.: 2). The specification and claims limit the number of amino acid substitutions, deletions, insertions and/or additions that may be made to SEQ ID NO.: 2, also in accordance with the Guidelines. Thus, the scope of the claims are based on the numerous known structural features of transcription factors, e.g., the genus is of limited variance due to the know structural features of transcription factors, some of which have even been crystallized. Even under the Guidelines a significant number of structural differences between genus members is permitted. The specification clearly states that these types of changes are routinely done in the art, and provides specific guidance as to what changes should be made, e.g., to the subunits and/or the other structural features that the skilled artisan will recognize as summarized in FIGs 8A, 8B, 9 and the specification. Structural features that distinguish specific

region III, proline, serine and threonine rich regions as well as clathrin like domains. Using

general knowledge and the level of skill in the art it would be possible to, e.g., swap domains of the factors that fall within the percentages of identity as claimed. Withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. §102

Claims 93-96 and 104-107 are rejected based on the cloning of TFIIA, which is only 66.3% identical at the nucleic acid level (at its best matching location) and was further purified. In order for a rejection under 35 U.S.C. §102(b) to be proper, the cited reference must teach each and every aspect of the claimed invention either explicitly or impliedly. See MPEP §2131. As elaborated in Richardson v. Suzuki Motor Co. "[t]he identical invention must be shown in as complete detail as is contained in the claim." 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1987). PPG Industries, Inc. v. Guardian Industries Corp., 75 F.3d 1558, 1566, 37 U.S.P.Q.2d 1618, 1624 (Fed. Cir. 1996)("a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.").

Applicant fails to see how Ma, et al.'s teaching of: (1) a fusion protein partner, with (2) TFIIA, a protein that is only 66.3% identical at the DNA level, constitutes enablement of "each and every element of the claimed invention." The Action also states that, "[a]s a single amino acid constitutes a portion of a TFIIAα/β-like factor protein, Ma et al. teach a fusion protein comprising a portion of a TFIIAα/β-like factor protein and a non- TFIIAα/β-like factor protein sequence." As the claims are not directed to a single amino acid, but rather, a protein having a particular, novel amino acid sequence, the basis of the rejection is far from clear. The protein taught by Ma, et al., is not the same protein as claimed herein, merely adding a fusion protein portion, e.g., a his-tag, is by no means "each and every element" of the claimed invention.

For the above reasons, Applicant submits that the Ma, et al. sequence does not anticipate the claimed fusion protein within the meaning of § 102 (In re Bond, 15 USPQ2d 1566 (Fed. Cir. 1990), "For a prior art reference to anticipate in terms of 35 USC §102, every element of the claimed invention must be identically shown in a single reference.").

factor protein," and "Stoned TFIIAα/β-like factor protein." Withdrawal of the rejection is respectfully requested.

CONCLUSION

Applicant respectfully requests that the Examiner reconsider and withdraw the outstanding objections and rejections, and allow claims 86-107. Applicant also requests that the Examiner call the undersigned for any reason that might advance this application to issue.

This Amendment does not increase the number of independent claims, does not increase the total number of claims, and does not present any multiple independent claims. Accordingly, no fee based on the number or type of claims is currently due.

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Respectfully submitted,

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